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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,485	09/15/2000	Nobuya Sato	197129US0PCT	7267

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,485

Applicant(s)

SATO ET AL.

Examiner

Isis Ghali

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-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment C, both filed 07/28/2003.

Claims 1-3, 7-10 are included in the prosecution.

1. This application contains claims 11-23 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Claim Rejections - 35 USC § 103

The standing rejection:

Claims 1-3 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,063,379 ('397).

The currently pending claim 1 recites a sheet comprising ingredient (A) that is 100 parts by weight of at least thermoplastic resin; ingredient (B) that is 0.01 to 200 parts by weight of medical ingredient; and at least one oily ingredient.

US '397 teaches a sheet (col.7, lines 24-27) comprising:

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Polyolefins: nylon 6, nylon 66, polyethylene terephthalate or polyvinyl acetate that are disclosed by applicants as thermoplastic resin, (col.5, lines 26, 49-63);

Active ingredients to be delivered to the skin or hair: anti-wrinkles, anti-inflammatory agents (col.17, lines 16-17; col.18, line 1; col.26, lines 49-56);

Agent selected from: mineral oils, vegetables oil, hydrogenated vegetable oil, alcohol esters, monoester and diester of fatty acids, and hydrocarbons that are disclosed by applicants as oily ingredients (col.13, line 60-col.14, line 35); and

Polyethylene and polypropylene and polyurethane that are disclosed by applicants as hard segment elastomer, and polyester that is disclosed by applicants as soft segment elastomer, and mixtures thereof (col.5, lines 26, 49-63).

The reference does not teach anywhere that the film has an adhesive layer and that meets the limitation of claim 2 as claim 2 recites that the sheet comprises no adhesive layer.

The reference differs from the instant claims because it does not teach the amounts of the different ingredients and the modulus.

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect, such as the modulus. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the thermoplastic resin and the active ingredient instantly claimed are not considered to impart a patentable distinction absent evidence showing

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unexpected and superior results. The prior art teaches the property of delivering active ingredients to the skin or hair.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, medical ingredient, and oily ingredient, and manipulate the amounts of the thermoplastic resin in order to achieve a particular modulus depending on the intended use of the sheet, motivated by the teaching of the reference that disclosed sheets can have non-limiting desirable characteristics depending on the material of the sheet, with reasonable expectation of success of the delivered sheet to have a particular modulus on stretching depending on its site of application to deliver active agent to the skin or hair from the sheet as desired by applicants.

Response to Arguments:

Applicants traverse the above rejection of claims 1-3, 7-10 by arguing that the US '397 describes a disposable single use personal care cleansing and conditioning product and nowhere the reference teaches that the product comprises oily ingredients to increase comfortability to the skin or hair. The reference does not teach the specific modulus claimed by applicants. The product of US '397 comprises leathering surfactant. No motivation in US '397 to modify the product in order to have the claimed modulus so as to conform to the skin or hair for a duration of time. Applicants argue that the office

relied on the disclosure of the present invention in order to supply motivation to alter the invention of the reference towards the claimed invention.

In response to the above arguments, the examiner position is that the reference discloses a sheet that used to deliver active agents to the skin or hair, not only cleansing product, col.17, line 17, and comprising the same three ingredients as disclosed by applicants including the thermoplastic resin, active agent and the oily ingredients. The intended use of the oily ingredients is not critical in claims directed to a product. The expression "comprising " permits the presence of other ingredients, such as the leathering surfactants, and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. The claimed modulus does not impart patentability to the product claims if the prior art teaches product comprising the same ingredients, absent evidence to the contrary. In response to applicant's argument that there is no motivation to modify the references in order to have the claimed modulus, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation arises

from the teaching of the reference that disclosed sheets can have non-limiting desirable characteristics depending on the material of the sheet, with reasonable expectation of modifying the modulus of the delivered sheet to have a particular modulus on stretching depending on its site of application to deliver active agent to the skin or hair with success. In response to applicant's argument that the examiner's conclusion of obviousness is based upon applicants' disclosure, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

3. Claim Rejections - 35 USC § 103

The standing rejection:

Claims 1-3, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32567 ('567).

WO '567 teaches a sheet comprising:

Olefin resins or polyamide resin such as nylon 6, nylon 66, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, polyacrylonitrile, polyester, polyethylene

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terephthalate, and polybutylene terephthalate that are disclosed by applicants as thermoplastic resin, (page 14, line 22 till page 15, line 22);

Cosmetic substance including whiting component and antiphlogestic component (page 20, lines 15-20);

Oily ingredient comprising natural oils and esters of fatty acids such as isopropyl myristate, and higher fatty acids (page 19, lines 11-19);

Thermoplastic elastomer comprising styrene, polyurethane, polyester that are disclosed by applicants as hard segment, (page 14, lines 5-15; page 15, lines 23-25); and polyester, ethylene-propylene-diene monomer terpolymer, polyethylene, and polypropylene that are disclosed by applicant as soft segment, (page 14, lines 5-15; page 15, line 15).

The reference disclosed that the sheet is not easily torn in the course of peeling off and does not cause any remains of the film on the surface of the skin during peel off and it is not sticky (page 6, lines 17-22).

The reference does not teach the amount of the thermoplastic resin and the medical ingredient or the modulus of the sheet.

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect, such as the modulus. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the thermoplastic resin and the active ingredient instantly claimed are not considered to impart patentable distinction absent evidence showing

unexpected and superior results. The prior art teaches the property of delivering active ingredients to the skin or hair from the sheet, as desired by applicants.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, medical ingredient, and oily ingredient, and manipulate the amounts of the thermoplastic resin in order to achieve a particular modulus depending on the intended use of the sheet, motivated by the teaching of the reference that the disclosed sheets having the thermoplastic resin and thermoplastic elastomer is not easily torn in the course of peeling off and does not cause any remains of the film on the surface of the skin during peel off and it is not sticky, with reasonable expectation of success of the delivered sheet to have a particular modulus on stretching depending on its site of application to deliver active agent to the skin or the hair.

Response to Arguments

Applicants traverse the above rejection of claims 1-3, 7-10 by arguing that WO '567 discloses a multilayered sheet pack comprising hydrophilic layer and hydrophobic layer. Thus, the reference teaches away from having the three claimed components in a single layer. The reference does not teach the claimed modulus or suggest it. Applicants argue that the office relied on the disclosure of the present invention in order to supply motivation to alter the invention of the reference towards the claimed invention.

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In response to the above argument, the examiner position is that the instant claims are directed to a sheet, and not claiming single layered sheet. The claims read as a sheet, that could have more than one layer, and one of the layers of the sheet incorporates the tree ingredients. WO '567 teaches that one of the layers comprises thermoplastic resin that kneaded as a film with an oily component, page 16, lines 15-16. Thus, the resin, the oily component and the active agent are all incorporated in the same layer. The claims' language does not exclude the presence of other layers in the sheet. The claimed modulus does not impart patentability to the product claims if the prior art teaches product comprising the same ingredients, absent evidence to the contrary. In response to applicant's argument that there is no suggestion in the references to the claimed modulus, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation arise from the teaching of the reference that the disclosed sheets having the thermoplastic resin and thermoplastic elastomer and the oily component is not easily torn in the course of peeling off and does not cause any remains of the film on the surface of the skin during peel off and it is not sticky, with reasonable expectation of the delivered sheet to have a particular modulus on stretching depending on its site of

application to deliver active agent to the skin or the hair with success. In response to applicant's argument that the examiner's conclusion of obviousness is based upon applicants' disclosure, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

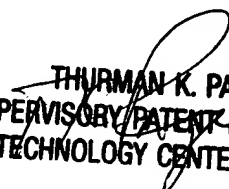
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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600